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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MABRY, JOHN	
ART UNIT	PAPER NUMBER
1609	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,733	NAGAI ET AL.	
	Examiner	Art Unit	
	John Mabry	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/05 and 4/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Objections

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which claims are directed.

Claim 8 is objected to because of the following informalities: Claim 8 is dependent on claim 6 and sites substituent X_1 as described in claim 6. Claim 6 does not describe substituent X_1. Examiner will interpret X_1 as described in claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble "... a pharmaceutical composition..." is vague. If applicant is claiming a pharmaceutical composition, the claim does not have a pharmaceutically acceptable carrier, excipient or diluent.

Claims 20 and 22 – 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble in claim 20 "The medicine

comprising of the compound..." is vague and does not further limit itself from claim 1. The preamble "The medicine according to..." of claims 22 – 38 are also considered vague and is not considered further limiting according to the scope of claim 1.

Claims 42 - 45 provide for the use of "manufacturing an agent of claim 1", but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 - 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for hydrates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Claims 1 - 21 are drawn to hydrates, but the numerous examples presented all failed to produce a hydrate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there

is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that hydrates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Claims 39 - 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative

skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

In the instant case, claims 39 - 41 are not enabled for a method treatment of angiogenesis related diseases. If the "use" claims, 42 – 45, are drawn to methods of treating angiogenesis related diseases, they are encompassed by this rejection.

Nature of the Invention

The nature of the invention is broadly drawn to a method of treatment of angiogenesis related disease comprising administering a therapeutically effective amount of an angiogenesis modulating compound (as described in claim 1). The essential aspect that necessitates the enablement rejection is not the composition of claim 1, but the claim to its use in a pharmaceutical manner. In addition, the scope of the claims encompasses methods of gene therapy.

Skill of those in the Art

The level of skill in the art is high because of experimentation may be expansive and unpredictable.

The Breadth of Claims

Current treatments for the diseases covered by the scope. Any one drug cannot treat these diseases and disorders, disclosed in the specification on pages 103, generally. These are all different diseases and disorders, which occur at different locations and by different modes of action in the body. The specification is drawn to an elaborate list of different cancers, all of which cannot be treated by any one drug.

Cervical cancer, just one of the many cancers mentioned, is treated by surgery, radiation therapy, and chemotherapy.

Working Examples and Guidance Provided

The specification does not demonstrate support for modulating angiogenesis in an individual, using recombinant molecules of claim 1. There are no working examples of modulating angiogenesis in an individual. Rather, the specification describes using the compounds of claim 1 in cell culture experiments. Further, the applicant does not specify which compound encompassed by claim 1 was used in the tissue culture experiments.

In addition, the claims encompass treating any and all angiogenesis-related diseases. The specification lists a large number of cancers which could be treated with the compounds of claim 1, including cancer types, such as: the solid cancer include pancreate cancer, stomach cancer, colon cancer, breast cancer, prostate cancer, lung cancer, renal cancer, brain tumor, head and neck cancer, esophagus cancer, skin cancer, hepatic cancer, uterine cancer, uterine cervix cancer, bladder cancer, thyroid cancer, testicular tumor, villus cancer, osteosarcoma, soft-tissue sarcoma and ovarian cancer. The compound is particularly preferably used for cancers such as a colon cancer, breast cancer, prostate cancer, lung cancer, head and neck cancer, and ovarian cancer. Further, the compound is also effective as an antitumor drug against leukemia. (page 103, lines 8-19) However, there are no examples using art recognized models of these diseases.

Test example 3 (page 101) of the specification describes the transcription of cancer cells with a reporter gene construct, causing inhibition of VEGF in the cell line. These examples are not applied to individuals having angiogenesis related diseases or animals having tumors.

Therefore, no data is provided in the specification that teaches how to modulate angiogenesis modulation as a result of the treatment with the compounds of claim 1 as a therapy for angiogenic related diseases.

State of the Art and Analysis of the Issues

The nature of the invention is a method of gene therapy; the state of the prior art is not well developed and is highly unpredictable. According to the specification, applicant's compounds of formula I (pages 100 – 103) are alleged to exhibit inhibitory activity during *in vitro* studies. However, the specification does not set forth the specific compounds that were used in the *in vitro* assays. Even if the exact compounds were disclosed, there are no teachings of how to use the claimed compounds *in vivo*.

The language of the claims is not strictly limited to *in vitro* treatments and encompasses treating patients and as such do not have support in the specification. There is insufficient disclosure to reasonably predict that the methods and compositions of the instant specification would suppress VEGF production, control gene expression and inhibit angiogenesis *in vivo*. This is merely an unsubstantiated assertion with no evidence to support the contention that the *in vitro* studies of the specification are indicative of *in vivo* activity. Applicant has only shown cell culture data, not treating affected patients or shown an art recognized correlation between the data shown and

the scope of the claimed invention. The artisan would recognize and appreciate that there is no known correlation between *in vitro* and *in vivo* results, because the artisan recognizes that an *in vitro* assay cannot duplicate the complex conditions of *in vivo* therapy. In the *in vitro* assay, the agent is in contact with cells during the entire exposure period. This is not the case *in vivo* where exposure to the target site may be delayed or inadequate. In addition, variables such as biological stability, half-life, or clearance from the blood are important parameters in achieving successful therapy. The composition may be inactivated *in vivo* before producing a sufficient effect, for example, by proteolytic degradation or immunological activation. In addition, the composition may not reach the target cells because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells, and tissues where the composition has no effect and/or a large enough local concentration may not be established. There are no specific teachings in the disclosure that would allow one to have a reasonable expectation of success in transferring the *in vitro* method to treat affected patients. One is only left with speculation and an invitation to experiment. In addition, because angiogenesis is a complex process, involving numerous, diverse molecules, interacting with vascular endothelium throughout the process, it is difficult to demonstrate that the molecules of claim 1 are either the inhibitor of a cascade that results in growth of blood vessels or solely responsible for inhibiting angiogenesis. Therefore, the claimed invention lacks an enabling disclosure

Given the breadth of the claims which encompass modulating angiogenesis in an individual and the lack of examples and guidance as discussed above, one skilled in the

art would reasonably have considered that at the time the application was filed, undue experimentation would have been required to use the claimed invention to successfully modulate angiogenesis in an individual, by the claimed method.

Claims 22 - 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of written description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claims 22 - 45 are broadly drawn, such that it applies to a genus of diseases. However, the working examples provided in the instant application are only directed to individual inhibition of angiogenesis in tissue culture. The instant specification lists

various cancer types, such as: the solid cancer include pancreate cancer, stomach cancer, colon cancer, breast cancer, prostate cancer, lung cancer, renal cancer, brain tumor, head and neck cancer, esophagus cancer, skin cancer, hepatic cancer, uterine cancer, uterine cervix cancer, bladder cancer, thyroid cancer, testicular tumor, villus cancer, osteosarcoma, soft-tissue sarcoma and ovarian cancer. The compound is particularly preferably used for cancers such as a colon cancer, breast cancer, prostate cancer, lung cancer, head and neck cancer, and ovarian cancer. Further, the compound is also effective as an antitumor drug against leukemia. (page 103, lines 8-19) These examples of diseases do not encompass the enormous range of afflictions that affect mammals. There is no further description of the term, "disease".

Although the specification lists many cancer types, there are no examples of treating diseases in animal models. The sole reference to mouse or mice is on page 102, lines 17, where there is an extrapolation of cell culture data, such that the applicant interprets the data to mean that there is a non-toxic effect on whole animals. Nevertheless, there is no demonstration of antitumor effect on animal models presented in the instant application.

The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, p1 "Written Description" Requirement (Federal Register/ Vol 66. No 4, Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS,

ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (column 2, page 71436, emphasis added).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Considering the potentially large numbers of diseases encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement

thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 42 - 45 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 71 and 73 – 92 of U.S. Patent No. 7,026,352 B1.

Claims 1 – 38, compounds, compositions, and medicaments thereof, are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 67 and 73 – 92.

The instant Application claims compounds of formula I wherein R^7 = -O-(C=O)Et and R^{21} = -OEt at the R^7 and R^{21} positions.

7,026,352 discloses compounds of formula I, wherein R^7 = -O-(C=O)Me and R^{21} = -OMe at the R^7 and R^{21} positions (see compound B8-1, column 119, line 17).

7,026,352 differs from the instant claims in the substituents at the R^7 and R^{21} positions. A methoxy (-OMe) group is considered a homolog of ethoxy (-OEt) at the R^{21} position and -O-(C=O)Me is a homolog of -O-(C=O)Et at the R^{21} positions. There may be others as well. Thus, an obviousness-type double patenting exists.

Furthermore, the generic formula 2 (column 200, line 20) teaches R^7 = $-N(CH_3)_2$, -O-(C=O)Ph, and $-O-(C=O)C_5H_4N$ and R^{21} = $-N(CH_3)_2$, $-O(C=O)CH_2CH_3$, and $-O-(C=O)N(CH_2)_4$ as alternatively useable. Thus, said claims are rendered obvious by 7,026,352.

The MPEP 2144.09 which states: Compounds which are homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

The instant Application claims compounds of formula I wherein R^7 = -O-(C=O)Et, R^{20} = H, and R^{21} = F.

7,026,352 teaches compounds of formula II, wherein R^7 = -O-(C=O)Me, R^{20} = F and R^{21} = H (see compound B18-3, column 129, line 60).

a) The same homolog argument applies, wherein the MPEP 2144.09 which states: Compounds which are homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

(b) 7,026,352 differs from instant claims in the substituents at the R^7 and R^{21} positions. According to the applicants claim 1, R^{20} = H and R^{21} = F. 7,026,352 reads on this claim wherein compound B18-3 where fluorine is at the R^{20} = F and R^{21} = H.

There is little difference between the fluoro substituent being at the 20-position as compared t the 21-position on the tail of the 12-membered macrolide structure. It is well established that position isomers are prim facie structurally obvious even in the absence of a teaching to modify. The isomer is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This circumstance has arisen many times. See: *Ex parte Englehardt,* 208 USPQ 343, 349; *In re Mehta,* 146 USPQ 284, 287; *In re Surrey*, 138 USPQ 67; *Ex Parte Ullyot,* 103 USPQ 185; *In re Norris,* 84 USPQ 459; *Ex. Parte Naito,* 168 USPQ 437, 439; *Ex parte Allais,* 152 USPQ 66; *In re Wilder,* 166 USPQ 545, 548; *Ex parte Henkel,* 130 USPQ 474; *Ex parte Biel,* 124 USPQ 109; *In re Petrzilka,* 165 USPQ 327; *In re Crownse,* 150 USPQ 554; *In re Fouche,* 169 USPQ

431; *Ex parte Ruddy,* 121 USPQ 427; *In re Wiechert,* 152 USPQ 249, *In re Shetty,* 195 USPQ 753; *In re Jones,* 74 USPQ 152, 154. There may be others as well. Thus, an obviousness-type double patenting exists.

For example, "Position isomerism has been used as a tool to obtain new and useful drugs" (*Englehardt*) and "Position isomerism is fact of close structural similarity" (*Mehta*, emphasis in the original). Note also *In re Jones,* 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to prima facie obviousness"; one of those listed is "adjacent homologues and structural isomers". Position isomers are the basic form of close "structural isomers." Similar is *In re Schechter and LaForge,* 98 USPQ 144, 150, which states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also *In re Deuel* 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds...a known compound may suggest it analog or isomers, either geometric (cis v. trans) or position isomers (e.g. ortho v. para)." See also MPEP 2144.09, second paragraph. Further, the reference provides for the ring being substituted in any position.

Claims 39 - 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 68 - 71 over 7,026,352. The instant application claims (39-41) cites a method of preventing or treating a disease for which

gene expression control is effective, suppression of VEGF production is effective, and angiogenesis inhibition is effective according to claim 20.

7,026,352 teaches in claims 68 (column 228, line 64), 69 (columns 229, line 1), 70 (column 229, line 6), and 71 (column 229, line 10) where a method for gene expression control, VEGF production, antiangiogenic effect are all efficacious according to claim 50. Claim 50 (7,026,352) refers to compounds of claims 1- 49 which are not identical, but the scope of the current application overlaps in scope to the referred compounds with the referenced patent. Claims 42 – 45 are "use of the compound" claims (that reads on the previously mentioned diseases) are also rejected. The examiner has interpreted the "use" claims of claims 42 - 45 as being drawn to methods of treating angiogenesis related diseases.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry whose telephone number is (571) 270 - 1967. The examiner can normally be reached on Monday - Friday from 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on Monday - Friday from 9 am to 5 pm. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JM

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER